Can Vessel Preparation Minimize Residual Stenosis and Improve Outcomes?

Professor Thomas Zeller
Department of Angiology
University Heart Center Freiburg-Bad Krozingen
Bad Krozingen, Germany
Faculty Disclosure

Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

• **Honoraria received from:** Abbott Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Shockwave

• **Consulted for:** Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, Veryan, Intact Vascular, B. Braun, Shockwave, Bayer, Vesper Medical

• **Research, clinical trial, or drug study funds received from (institution):** 480 biomedical, Bard Peripheral Vascular, Veryan, Biotronik, Cook Medical, Gore & Associates, Medtronic, Philips, Terumo, TriReme, Shockwave, Med Alliance, Intact Vascular, B. Braun

• **Common stock:** QT Medical
Purpose of Vessel Preparation

Creates an optimal environment for angioplasty:

- Improves vessel compliance
  - Lower balloon pressures required for lesion effacement

- Increases luminal gain

- Facilitates drug distribution

- Minimize adverse events
  - Dissections, embolization, perforations

- Decreases the need for stenting
FLEX Vessel Preparation System

Sheath Size 6 French

Wire Compatibility .014 and .018

Catheter Length 40cm and 120cm

3 Atherotomes (Proximal) 0.01” in Height

CE Mark / FDA Indication for Use: To facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae
The FLEX System

- 3 Proximal Atherotomes Mounted on Skids
- Controlled Depth Micro-Incision
- Retrograde Pull-Back
- Rotation Control (1:1 torque)
- A One Size Fits All

OCT Image of Micro-Incision

Histology of Micro-Incision
Mechanism of Action

- Precise longitudinal micro-incisions
- Skid surface area prevents perforation
- Atherotomes interact with vessel surface at 1 atm
- Creates a controlled environment for angioplasty
- Basket “flexes” to plaque contour
Parallel FLEX Micro-Incisions

Human cadaver SFA, SEM Image magnified 150x
Acute Real-World Data

- 457 Patients treated
- 66 Institutions, 100 Physicians

Definitions:

Procedural Success: Residual Stenosis ≤ 30%
Opening Balloon Pressure: Lowest pressure required to fully efface the lesion.

- Average Age: 71 years old
- Average Lesion Length: 13.7 cm
- Chronic Total Occlusions: 44%
- Average Baseline Stenosis: 92%
Vessel Preparation by the FLEX

- Angiogram is Captured Prior to Angioplasty Evaluating Luminal Gain and Safety of the FLEX.

Post FLEX Alone:
Average Luminal Gain: 29.5%
Procedural Results

- DCB utilized in 73% of cases
- Average Opening Balloon Pressure: 4.5 atm

<table>
<thead>
<tr>
<th>Dissection Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade A Dissections</td>
<td>4.6%</td>
</tr>
<tr>
<td>Grade B Dissections</td>
<td>1.3%</td>
</tr>
<tr>
<td>Flow-Limiting Dissection</td>
<td>0%</td>
</tr>
<tr>
<td>Perforation</td>
<td>0%</td>
</tr>
<tr>
<td>Embolization</td>
<td>0%</td>
</tr>
</tbody>
</table>

- No Bail-Out Stenting Required
- Provisional Stent Use: 21.7%
- Average Residual Stenosis: 10%

- Procedural Success: 97.2%
Stent Cohort

- No Flow-Limiting Dissections
- All Provisional
- Increased Average Lesion Length (cm)
- Higher percentage of CTOs

- No Change to FLEX Luminal Gain or Residual Stenosis
Conclusion

• Vessel preparation with the FLEX System achieved a high rate of procedural success. \( \frac{3}{4} \) cases used DCB post FLEX.

• Low opening balloon pressures suggest improvement in vessel wall compliance with use of the FLEX. Low dissection rate with no flow-limiting dissections.

• All stenting was provisional; longer lesions and CTOs tended towards stenting.

• Further studies are warranted on the long-term benefits.
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